UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,615	06/13/2001	Michael W. Johnson	S63.2-9949	7299

490 7590 10/23/2006

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER	
COZART, JERMIE E	

ART UNIT	PAPER NUMBER
3726	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/880,615
Filing Date: June 13, 2001
Appellant(s): JOHNSON, MICHAEL W.

MAILED
OCT 2 3 2006
Group 3700

James M. Urzedowski
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/24/05 appealing from the Office action mailed 6/24/05.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,843,172	Yan	12-1998
5,769,884	Solovay	06-1998
5,807,404	Richter	09-1998

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 23, 26-30, 32, 35-37, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan (5,843,172) in view of Solovay (5,769,884).

Regarding **claim 23** and **26-30**, Yan discloses a method of manufacturing a stent comprising providing a tube having at least two different longitudinally spaced regions of different predetermined physical characteristics (different pore sizes located along the stent). The tube is formed from metal which is sintered and thereby provided as porous thereby having regions of differing porosity. The stent is cut from the tube after the tube has been formed from sintered metal. A treatment agent (i.e. therapeutic drugs) is disposed on the stent. Yan discloses a stent (12) having been formed according to one embodiment, it is clearly apparent that since Yan discloses forming a stent from a porous tube via laser, it is there safe to surmise that the stent (12) in figure 1 has been formed in the same manner (i.e. laser cutting), wherein stent (12) includes a plurality of serpentine segments extending about the circumference of the stent. As a result of this laser cutting, a plurality of elongate openings is formed whose widths exceed their

lengths. *See column 2, lines 7-14 and 39-46; column 3, lines 55-60; column 4, lines 1-11 and 32-65; column 7, lines 30-51; and Figures 1-3 and 6 8 for further clarification.*

Regarding **claims 32, 35-37, and 39**, Yan discloses manufacturing a stent, wherein a tube of sintered metal is provided having different predetermined porosities. The tube is cut using a laser thereby forming a plurality of openings in the tube which in turn creates a stent (12) as previously rationalized above having multiple serpentine bands. A treatment agent (i.e. therapeutic agent) is disposed on the stent. Some of the openings are bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment. The openings which are bounded by at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment include a first side wall and a second side wall extending between and connecting the first and second serpentine segments. The first and second serpentine segments have different physical characteristics (i.e. different porosity). *See column 2, lines 7-14 and 39-46; column 3, lines 55-60; column 4, lines 1-11 and 32-65; column 7, lines 30-51; and Figures 1-3 and 6 8 for further clarification.*

Yan, however, does not disclose the following: the tube having at least two different longitudinally spaced regions of different predetermined porosities and each region having substantially the same porosity about its circumference, or a first portion of the tube being characterized by a first porosity and second portion of the tube, longitudinally spaced from the first portion of the tube, being characterized by a second porosity different from the first porosity; forming multiple serpentine bands such that a first band has a different porosity than a second band.

Solovay discloses a stent covering (30) which is formed into a tube around the stent wherein the tube has at least two different longitudinally spaced regions (12, 13) of different predetermined porosities (see Fig. 6) and each region having substantially the same porosity about its circumference, wherein a first portion (12) of the tube is characterized by a first porosity and second portion (13) of the tube, longitudinally spaced from the first portion of the tube is characterized by a second porosity different from the first porosity. Solovay allows the proper amount of therapeutic agents to be delivered to the treatment site. *See column 3, line 66 – column 4, line 10; column 4, lines 44-49; column 6, lines 47-53; and figures 2, 6, 6A, and 6D for further clarification.*

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the tube of Yan with at least two different longitudinally spaced regions of different predetermined porosities wherein each region has substantially the same porosity about its circumference, and wherein a first portion of the tube is characterized by a first porosity and second portion of the tube, longitudinally spaced from the first portion of the tube, is characterized by a second porosity different from the first porosity, in light of the teachings of Solovay, in order to effectively deliver the desired amounts of therapeutic agents to a particular treatment site within the human body.

Claims 24, 33, 38, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan/Solovay as applied to claims 23, 32, 37, and 40 above, and further in view of Richter (5,807,404).

Yan/Solovay as modified above discloses all of the claimed subject matter except for the following: a first portion of the tube being made from a first metal and a second portion of the tube, axially spaced from the first portion of the tube being made from a second metal different from the first metal; the first and second side walls being non-parallel to the longitudinal axis of the stent; or at least some of the openings being bounded at a proximal end by a first serpentine segment made of a first metal and at a distal end by a second serpentine segment made of a second metal different from the first metal.

Richter discloses a stent (1) having at least two longitudinally spaced regions (8, 9) and (8`,9`) of different predetermined physical characteristics. A first portion (8, 9) of the tube is made from a first metal and a second portion (8',9') of the tube, longitudinally spaced from the first portion is made from a second metal different from the first metal. Richter discloses a plurality of serpentine bands or segments (Fig. 11) extending about the circumference of the stent, and at least some of the openings being bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment. The first and the second side walls (Fig. 11) are non-parallel to the longitudinal axis of the stent. The first and second serpentine segments having different physical characteristics. Richter discloses at least some of the openings being bounded at a proximal end by a first serpentine segment made a first metal and at a distal end by a second serpentine segment made of a second metal different from the first metal. *See column 1, lines 36-54; column 1, line 66 – column 2, line 2; column 4, lines 32 – 40; column 6, lines 5-7, lines 42 – 51, and lines 57-60; column 7, line 63 – column 8, line 22; and Figures 1, 2, and 7-11 for further clarification.*

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the tube of Yan/Solovay with a first portion of the tube being made from a first metal and a second portion of the tube, axially spaced from the first portion of the tube being made from a second metal different from the first metal such that the first and second side walls are non-parallel to the longitudinal axis of the stent; and to provide at least some of the openings being bounded at a proximal end by a first serpentine segment made of a first metal and at a distal end by a second serpentine segment made of a second metal different from the first metal, in light of the teachings of Richter, in order to provide more flexibility at the ends to allow the stent to accommodate the curvature of a vessel in which the stent is implanted.

(10) Response to Argument

Appellant states that Yan teaches at column 4, lines 58-64, uniform porosity and the undesirability of areas of different porosity. Appellant further states that the explicit language of the Yan reference teaches the undesirability of areas of different porosity, and that it does not make sense that Yan would teach longitudinally spaced regions of different predetermined physical properties. Appellant finally states that Yan teaches away from the very combination from such a teaching, and that one [presumably of ordinary skill in the art] would never predetermine to produce the very thing that is undesirable (i.e. non-uniform porosity).

In response, the Examiner states that the portion of Yan cited by Appellant is taken out of context and in Yan at column 3, lines 65-67, there is a teaching of porous cavities (18) which range in size between 0.01 and 20 microns. Yan further states in

column 4, at lines 58-64 states that "Consistent pore size is also important to ensure that drugs are evenly distributed throughout the stent". Therefore, the teachings provided by Yan would in fact lead one of ordinary skill in the art to arrive at the conclusion that with consistent pore size, the porosity of different regions of the stent can be different even though the porosity within a particular region of stent can be consistent. The fact that Yan discloses "consistent pore size (col. 4, lines 6-21)" not total "uniform porosity" does not preclude the fact that the porosity of the stent can vary depending upon pore size as evidenced by Yan's disclosure at column 3, lines 65-67. In response, the Examiner states that there is no explicit language in Yan teaching the undesirability of areas of different porosity as Appellant's citation of Yan fails to support this theory and further Yan makes no further mention of the undesirability of areas of different porosity.

Appellant states that motivation to make the combination [of Richter with Yan and Solovay] is lacking in that Richter neither teaches nor suggests the desirability of providing a stent with different porosities. Appellant additionally states that motivation to make the combination is lacking in Solovay which discloses a stent covering for use on a stent without any suggestion of the porosity being within the stent itself.

In response, the Examiner states that Richter was not cited to show providing a stent with different porosities. The teaching of providing a stent with different porosities is evidenced by the combination of Yan in view of Solovay. The purpose of Solovay with respect to its combination with Yan is to show that an implantable tube inserted into a lumen within the body can be provided with longitudinally spaced regions of different

predetermined porosities. The teachings of Solovay with respect to the tube (30) enable one of ordinary skill in the art to ascertain that since the pores of the tube (30) can be filled with a material (i.e. drug or protein), then the delivery of the drug depends upon the longitudinal porous layout of the tube (30). Therefore, since Yan already teaches a porous stent and the desire for "consistent pore size" throughout a portion of the stent, one of ordinary skill in the art would have looked to Solovay based on the teaching that "consistent pore size" and subsequently uniform porosity can be maintained within a region yet the porosities between different regions can also be different. The deficiencies that Appellant has reiterated are taught by the base reference to Yan which have been disclosed in the detailed rejection above.

Appellant states that the combination of Yan, Solovay, and Richter does not teach or suggest providing a tube having at least two different longitudinally spaced regions of different predetermined porosities and subsequently cutting the tube into a stent. Appellant states that the stent cover of Solovay functions properly when placed about a stent and there is no disclosure that it possesses the requisite steer quality of a structure capable of supporting a body lumen, and thus, any cutting performed on the tube in Solovay does not form a stent as claimed in claim 23 or claim 32, but instead it forms a stent cover which is then placed about a stent.

In response to Appellant's arguments against the references individually, the Examiner states that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091,

231 USPQ 375 (Fed. Cir. 1986). The cutting steps that Appellant contends are not taught or suggested by Solovay are disclosed by Yan as outlined in the above rejection. The critical teaching in Solovay is varying porosity throughout the length of the delivery device (30), and in addition the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In summary, Appellant states that the Examiner is using impermissible benefit of hindsight when rejecting claims 23 and 32 for obviousness, and that the Examiner has not shown any teaching or motivation to combine the references.

In conclusion, the Examiner states it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, Yan teaches providing a stent with varying degrees of porosity so long as there is consistent pore size. Solovay teaches providing a tube for insertion within a body lumen having a pattern of porosity, wherein the regions of porosity may be different and are longitudinally spaced. Therefore, one of ordinary skill in the art would have looked to

the teachings of Solovay in order to modify Yan and arrive at Appellant's claimed invention.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

JERMIE E. COZART
PRIMARY EXAMINER

Conferees:

David Bryant, *SPE AU 3726*

Monica Carter, *SPE AU 3722*